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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,269	01/05/2001	Antoinette F. Antignani	P-3734C1C1	6898

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/05/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/755,269

Applicant(s)
Antignani et al.

Examiner
Ralph Gitomer

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 5, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other: _____

The IDS received 5/17/01 has been entered and claims 1-18 are currently pending in this application. Priority is granted to 5/4/1999.

5 Applicant's election without traverse of Group I, claims 1-18, in Paper No. 5 is acknowledged.

It would appear the point of novelty of the present invention resides in stabilizing heparinase with trehalose.

10

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20 Claims 1-3, 5, 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmermann.

Zimmermann (5,262,325) entitled ~~Method~~ Method for the Enzymatic Neutralization of Heparin ~~teaches~~ teaches in columns 7 and 8, Example 2, stabilization of heparinase. Compounds shown to stabilize heparinase include ammonium sulfate and some saccharides.

25 All the features of the claims are taught by Zimmermann for the same function as claimed. Regarding the claimed buffers, no novelty is seen in diluting enzymes with known buffers.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
10 negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various
15 claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the
20 examiner to consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6, 7, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zimmermann in view of
25 Baugh.

Zimmermann (5,262,325) entitled ~~Method~~ Method for the Enzymatic Neutralization of Heparin~~teaches~~ teaches in columns 7 and 8, Example 2, stabilization of heparinase. Compounds shown to stabilize heparinase include ammonium sulfate and some saccharides.

The claims differ from Zimmermann in that they recite the specific saccharide is trehalose.

Baugh (5,972,712) entitled ~~the~~Heparin Independent High Sensitivity Platelet Function Evaluation Technique ~~with~~ with a 102(e) date of 4/30/1997, teaches in column 17 lines 7-9, heparinase solutions with trehalose which is added to a buffered solution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ trehalose in the composition of Zimmermann as shown by Baugh because trehalose is a non-reducing saccharide and Zimmermann teaches other non-reducing saccharides. To select any known non-reducing saccharide as a stabilizer with the expected result would have been obvious in view of Zimmermann. And Baugh teaches the combination of heparinase, buffers and trehalose as a composition for testing blood coagulation.

Claims 1-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 ~~a~~ stabilizer ~~functionally~~ functionally describes a composition but does not do so sufficiently to determine the metes and bounds of the term. What is stabilized for example? In claim 6 it is unclear if a comma is intended after ~~sodium~~.

In claim 8 and all occurrences, there is inconsistency between amount and concentration. Claim 12 cannot be understood where the concentration of buffer in the 15 mL is not known.

5 The title of the invention is not aptly descriptive in view of the restriction. A new title is required that is clearly indicative of the invention to which the claims are directed.

10 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Antignani (6,187,553) is a parent case.

Baugh (6,010,911) teaches evaluating platelet function.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the
20 examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent
25 application information 7 days per week, or for filing

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applications electronically, please visit our website at
www.uspto.gov and click on the button Patent Electronic Business
Center for more information.

Ralph Gitomer

Ralph Gitomer
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